REMARKS

Claims 110-115, 117 and 118 are pending. Claims 110, 113 and 114 have been amended to more particularly define the present invention, as well as to correct inadvertent typographical errors. New claims 117 and 118 are particularly directed to compounds recited in the Markush group of claim 110, from which both new claims depend. No new matter has been added. As the amendment is merely to clarify that which was originally intended by the claim, Applicant respectfully presents that the scope of the claims has not be changed by this amendment.

Specifically, the present invention includes the administration of one of the compounds recited by claim 110 in order to treat syndrome X. However, even if the cited references, as discussed in the Amendment of November 12, 2002, teach to administer one or more of the recited compounds to a patient exhibiting a symptom of another disease or condition which may also be a symptom of syndrome X, the purpose of such an administration is not disclosed as being to treat syndrome X. Thus, because the references fail to disclose or suggest that the presently recited compounds as being useful in treating syndrome X, reconsideration of the rejection is requested.

As discussed above, the present invention includes the treatment of Syndrome X of Reaven by, for example, reducing resistance to insulin. The cited references teach that certain somatostatin derivatives reduce insulin resistance by increasing insulin sensitivity by delaying the secretion of insulin. Since insulin resistance is a symptom of Syndrome X, the Office Action asserts it would necessarily have been obvious to use derivatives of somatostatin in treating Syndrome X. Further, the Office Action states that a high level of insulin is a symptom of Syndrome X, and therefore, the delay of the secretion of insulin is a treatment for Syndrome X. However, Applicant respectfully submits that this final statement is a misinterpretation of the references, as no such assertion is contained therein. Even if insulin resistance is a symptom of Syndrome X and the references teach that somatostatin derivatives are useful in treating insulin resistance, Applicant respectfully submits that it would not necessarily have been obvious to use

the compounds recited by claim 110, as the cited references do not relate to, nor identify Syndrome X.

While the presently claimed treatment is useful in treating Syndrome X, it is only the Applicant's assumption that the presently claimed treatment functions via the reduction of insulin resistance. Thus, it is entirely possible that the presently claimed treatment actually functions in a different manner, i.e., other than reducing insulin resistance, to treat Syndrome X.

From the most recent Office Action, it is apparently the Examiner's position that a high level of insulin is one symptom of Syndrome X. However, it is generally known that the treatment of a single symptom does not deal with all aspects of a particular disease or problem. In other words, treatment of an individual symptom is not necessarily an equivalent to treatment of a particular disease or condition.

Applicant additionally takes this opportunity to correct an inadvertent typographic error in the paragraph bridging pages 4 and 5 of the Amendment of November 12, 2002. Specifically, it is commonly known that Type I diabetes affects 10% of diabetics, while 90% of diabetics have Type II diabetes. Type II diabetes affects 5% of the mature population of the Western world. In contrast, Syndrome X affects 25% of the mature population of the Western world.

In particular the present invention relates to a specific syndrome which must be diagnosed in the particular patient. That is to say, the patient suffering from the syndrome must be defined and must be treated in a particular manner. There are specific diagnosis tools which enable a physician to diagnose the syndrome.

The present claims are directed to a long-term preventive therapy for the treatment of Syndrome X. The medicament therapy is aimed to reduce the risk factors of, inter alia, atherosclerotic blood vessel disease, hypertension, hyderlipidemia, and glucose intolerance from covert or overt diabetes, i.e., symptoms of Syndrome X.

Moreover, the presently claimed treatment reduces the tendency of blood to clot which is a result of a high level of plasminogen activator inhibitor 1 (PAI-1) in the blood. By reducing the level of PAI-1, the degree of blood clotting is reduced, thus reducing the danger of myocardial infarction (MI) and cerebrovascular accident (CVA). High level of PAI-1 is also a risk factor of Syndrome X.

Thus, the presently claimed treatment is used as a preventive and effective treatment for atherosclerotic blood vessel disease, which will prevent many cases of MI and CVA.

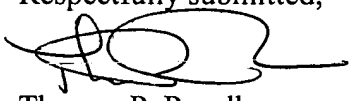
Finally, Applicant respectfully presents that while somatostatin and its derivatives have been used in the past to treat Type II diabetes, such compounds have not been used to treat Type I diabetes. However, insulin deficiency is present only in Type I diabetes. Thus, contrary to the assertion of the most recent Office Action, it is not known in the art, as embodied in the cited references, to treat insulin deficiency with somatostatin or its derivatives. Somatostatin and its derivatives are known only to be useful in treating Diabetic Ketoacidosis (which may occur in patients suffering from Type I diabetes, among others), for the purpose of inhibiting the secretion of glucagon to reduce the production of ketone bodies in the liver.

Additionally, somatostatin and derivatives thereof are also used in the art as a research tool for measuring insulin resistance in an individual to inhibit secretion of insulin. Thereafter, insulin and glucose are infused into the blood and known dosages of a given period of time, in order to calculate insulin resistance. Such a procedure is often performed to test the effectiveness of an administered drug in reducing insulin resistance.

Thus Applicant respectfully presents that the cited references do not teach or suggest the use of the compounds recited by claim 110 for the purpose of treating Syndrome X. Reconsideration is therefore requested.

In view of the above, it is respectfully submitted that all objections and/or rejections are overcome. Thus, a Notice of Allowance is respectfully requested.

Respectfully submitted,



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ATTACHMENT - Marked-Up Claim

110. (Twice Amended) A method of treating [treatment of symptoms] syndrome X comprising [by] administering to a patient exhibiting symptoms of syndrome X a pharmaceutical composition comprising [compositioncomprising] a pharmaceutically effective dosage of a compound selected from the group consisting of somatostatin or one of its analogs, diazoxide or one of its analogs, cyclothazide or one of its analogs and metaformin.

113. (Twice Amended) A method according to Claim 110, wherein the analog is Octreotide [Octrotide] which is applied in the form of an injection in a 0.9% saline solution.

114. (Twice Amended) A method according to Claim 110, wherein said dosage does not exceed 8 mg/kg/day in the treatment of the active ingredient in adults, and does not exceed 15[/]mg/day in the treatment of children.

115. (Twice Amended) A method according to Claim 110, wherein the amount of metaformin [metformin] applied does not exceed 2.5 g/day divided into 2-3 portions.